

### **REMARKS**

In view of the following remarks, the Examiner is respectfully requested to withdraw the rejections and allow Claims 1-12 and 18-19, as well as new Claims 20-24 the only claims pending and currently under examination in this application.

#### **Formal Matters**

Claims 1-12, 18-24 are pending after entry of the amendments set forth herein.

Claims 1-12 and 18-19 were examined. Claims 1-12 and 18-19 were rejected. No claims were allowed.

Claims 13-17 have been canceled.

Claims 1, 7-10, 12, 18-19 have been amended. Support for the amendments can be found in the claims as originally filed and throughout the specification at, for example: page 8, lines 19-31. Claims 1, 7-10, 12, 18-19 have been amended to address the Examiner's objection for failing to italicize the species/family name in the claims.

New claims 20-24 have been added. Support for new claims 20-24 can be found in the claims as originally filed and throughout the specification at, for example: Claim 20: original Claim 7, page 7, lines 29-37; Claim 21: original Claim 8, page 7, lines 29-37; Claim 22: original Claim 9, page 7, lines 29-37; Claim 23: original Claim 10, page 7, lines 29-37; and Claim 24: original Claim 18, page 7, lines 29-37.

As the above amendments introduce no new matter to the application, their entry is respectfully requested.

#### **Withdrawal of Objections and Rejections**

The Applicants express gratitude in the Examiner's indication that objections and rejections not repeated from the Office Action dated July 28, 2004, have been withdrawn.

#### **Objections to the Claims**

Claims 1, 7-10, 12, 18-19 have been objected for failing to italicize the species/family name in the claims. In view of the amendments to the claims, this objection may be withdrawn.

**Rejection under 35 U.S.C. § 112, first paragraph (Enablement)**

Claim 8 has been rejected under 35 U.S.C. § 112, first ¶ for an asserted lack of enablement, based on an asserted insufficient description of the term "stringent" in the specification. In view of the remarks made herein, this rejection is respectfully traversed.

As previously noted, the specification clearly defines the term stringent. See e.g., page 8, lines 19-31 which read:

Also provided are nucleic acids that hybridize to the above described nucleic acids under stringent conditions. An example of stringent hybridization conditions is hybridization at 50°C or higher and 0.1×SSC (15 mM sodium chloride/1.5 mM sodium citrate). Another example of stringent hybridization conditions is overnight incubation at 42°C in a solution: 50 % formamide, 5 × SSC (150 mM NaCl, 15 mM trisodium citrate), 50 mM sodium phosphate (pH7.6), 5 × Denhardt's solution, 10% dextran sulfate, and 20 µg/ml denatured, sheared salmon sperm DNA, followed by washing the filters in 0.1 × SSC at about 65°C. Stringent hybridization conditions are hybridization conditions that are at least as stringent as the above representative conditions, where conditions are considered to be at least as stringent if they are at least about 80% as stringent, typically at least about 90% as stringent as the above specific stringent conditions. Other stringent hybridization conditions are known in the art and may also be employed to identify nucleic acids of this particular embodiment of the invention.

However, in the spirit of expediting prosecution and without conceding as to the correctness of the rejection, claim 8 has been amended to recite "wherein said stringent conditions are at least as stringent as hybridization at about 50°C and about 0.1×SSC". Support for the amendment can be found in the specification at, for example, page 8, lines 19-31.

Accordingly, this rejection may be withdrawn.

**Rejection under 35 U.S.C. § 112, first paragraph (Written Description)**

Claims 1-2, 7, 9-12 and 18-19 have been rejected under 35 U.S.C. § 112, first paragraph, for allegedly lacking written description. This rejection is respectfully traversed as applied and as it may be applied to the pending claims.

In making this rejection, the Examiner asserts on page 5 of the office action that “the claimed nucleic acid is only defined by a function (encoding a protein) not a structure” (Office Action, page 4). In addition, the Examiner also states that “the claims encompass a genus of mutants not adequately described in the instant specification” (Office Action, page 5).

The law is clear that, if a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if not every nuance of the claims is explicitly described in the specification, then the adequate written description requirement is met.<sup>1</sup> Further, “an applicant ...is generally allowed claims, when the art permits, which cover more than the specific embodiment shown.”<sup>2</sup>

The Applicants maintain that the specification provides adequate written description support for such a disclosure. In particular, the Applicants respectfully submit that the specification provides abundant written description support for practicing the claimed invention. In particular, the Applicants note that the specification provides support for the subject nucleic acids at, for example, on page 6, line 23 through page 16, line 2; the particular interconverted aspect at, for example, on page 16, line 7 through page 17, line 16; exemplary methods of producing such mutants at, for example, on page 18, lines 7-12, and in greater detail on page 31, line 12 through page 34, line 38; resulting exemplary mutants at, for example, page 32, line 12, through page 34, line 20; constructs, vectors, expression cassettes, and expression systems including the subject

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<sup>1</sup> *In re Alton* 76 F.3d 1168, 37 USPQ2d 1578 (Fed. Cir. 1996).

<sup>2</sup> *Ethicon Endo-Surgery, Inc. v. United States Surgical Corp.*, 93 F.3d 1572, 40 USPQ2d 1019 (Fed. Cir. 1996).

nucleic acids at, for example, on page 11, line 3, through page 13, line 27; and applications using the subject interconverted mutants at, for example, on page 24, line 4, though page 30, line 6.

Furthermore the specification provides working examples demonstrating exemplary mutagenesis protocols for generating the subject nucleic acids encoding the far red shifted *Stichodactylidaen* chromoprotein or fluorescent mutants thereof (Example I, page 31), examples of mutants generated (page 32 to 34), and exemplary methods of generating and testing such far red shifted *Stichodactylidaen* chromoprotein or fluorescent mutant peptides (pages 34 to 36).

As noted by the Examiner in the Office Action, the pending claims are not limited to particular types of mutations, e.g., point mutations or single deletions, but encompass different types of mutations that result in an interconverted quality. The Applicants maintain that by showing specific examples of nucleic acids encoding far red shifted *Stichodactylidaen* chromoprotein or fluorescent mutants thereof (Example I, and pages 32 to 34), as well as providing a thorough description of DNA mutagenesis methods suitable for use with the present application (page 18), the Applicants have provided adequate written descriptive support for the scope of the claims.

In view of the above, it is submitted that the claims do comply with the written description requirement in that the claims are directed to nucleic acids encoding a far red shifted *Stichodactylidaen* chromoprotein or fluorescent mutant thereof. The specification provides multiple representative examples, including working examples of representative nucleic acids encoding exemplary mutant proteins, such that one of skill in the art would have no doubt that the applicant was in possession of the invention as claimed at the time the application was filed.

**Rejection Under Obvious-Type Double Patenting**

***Application No. 10/006,922 (Office Action, page 7)***

Claims 1-2, 7-12 and 18-19 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting over Claims 1-5, 8-10, 12-15, and 22-23 of co-pending Application No. 10/006,922. This rejection is respectfully traversed as applied and as it may be applied to the pending claims.

As noted above, the claims of the present application are directed to nucleic acids encoding a **far red shifted** *Stichodactylidaen* chromoprotein or fluorescent mutant thereof.

In contrast, co-pending '922 application is directed to nucleic acids encoding chromo- or fluorescent protein from non-bioluminescent *Cnidarian* species. The cited reference is silent as to a **far red shifted** *Stichodactylidaen* chromoprotein or fluorescent mutant thereof.

As set out in MPEP § 804 (see section II. B. 1.), in determining whether a nonstatutory basis exists for a double patenting rejection, the first question to be asked is - does any claim in the application define an invention that is merely an obvious variation of an invention claimed in the cited patent or application? An "obviousness-type" nonstatutory double patenting rejection might be appropriate only when the answer is "yes". A double patenting rejection of the obviousness-type is "analogous to [a failure to meet] the nonobviousness requirement of 35 U.S.C. § 103" except that the patent principally underlying the double patenting rejection is not considered prior art.<sup>3</sup> Therefore, any analysis employed in an obviousness-type double patenting rejection parallels the guidelines for analysis of a § 103 obviousness determination.<sup>4</sup>

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3 *In re Braithwaite*, 379 F.2d 594, 154 USPQ 29 (CCPA 1967).

4 *In re Braat*, 937 F.2d 589, 19 USPQ2d 1289 (Fed. Cir. 1991); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). As summarized at MPEP § 804, the factual inquiries are as follows:

- (A) Determine the scope and content of a patent claim and the prior art relative to a claim in the application at issue;
- (B) Determine the differences between the scope and content of the patent claim and the prior art as determined in (A) and the claim in the application at issue;
- (C) Determine the level of ordinary skill in the pertinent art; and

Moreover, MPEP § 2144.08 (II) states the following:

The patentability of a claim to a specific compound or subgenus embraced by a prior art genus should be analyzed no differently than any other claim for purposes of 35 U.S.C. 103.

...  
The fact that a claimed species or subgenus is encompassed by a prior art genus is not sufficient by itself to establish a *prima facie* case of obviousness. *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994)

As such, while the scope of the claims of the cited reference are directed to a broad genus of nucleic acids, claims directed to the narrower species are patentable within the broader genus. Therefore, the Applicants respectfully request that this rejection be withdrawn.

***Application No. 10/081,864 (Office Action, page 8)***

Claims 1-2, 7-12 and 18-19 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting over Claims 1-3, 5-9, and 15-16 of co-pending Application No. 10/081,864. This rejection is respectfully traversed as applied and as it may be applied to the pending claims.

However, the Applicants respectfully disagree. As noted above, the claims of the present application are directed to nucleic acids encoding a **far red shifted** *Stichodactylidaen* chromoprotein or fluorescent mutant thereof.

In contrast, co-pending '864 application is directed to nucleic acids encoding **non-aggregating** chromo- or fluorescent mutants of an aggregating *Cnidarian* chromo- of fluorescent protein or mutant thereof. The cited reference is silent as to a **far red shifted** *Stichodactylidaen* chromoprotein or fluorescent mutant thereof.

Accordingly, for the same reasons noted above, while the scope of the claims of the cited reference are directed to a broad genus of nucleic acids, claims directed to the

narrower species are patentable within the broader genus. Therefore, the Applicants respectfully request that this rejection be withdrawn.

***Application No. 10/155,809 (Office Action, page 8)***

Claims 1-12 and 18-19 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-16, 21 and 43 of co-pending Application No. 10/155,809. This rejection is respectfully traversed as applied and as it may be applied to the pending claims.

However, the Applicants respectfully disagree. As noted above, claims of the present application are directed to nucleic acids encoding a polypeptide product comprising a first and second chromo/fluorescent domain, optionally joined by a linking domain, wherein the first and second chromo/fluorescent domains associate with each other under intracellular conditions so that the encoded polypeptide assumes a tertiary structure.

In contrast, co-pending '809 application is directed to nucleic acids encoding a **kindling fluorescent protein** that goes from a first substantially non-fluorescent or non-fluorescent state to a second fluorescent state upon exposure to a kindling stimulus. The cited reference is silent as to a **far red shifted** *Stichodactylidaen* chromoprotein or fluorescent mutant thereof.

Accordingly, for the same reasons noted above, while the scope of the claims of the cited reference are directed to a broad genus of nucleic acids that may encompass kindling fluorescent protein species, claims directed to the narrower species of a **far red shifted** *Stichodactylidaen* chromoprotein or fluorescent mutant thereof are patentable within the broader genus. Therefore, the Applicants respectfully request that this rejection be withdrawn.

**CONCLUSION**

In view of the above remarks, this application is considered to be in good and proper form for allowance and the Examiner is respectfully requested to pass this application to issuance.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815.

Respectfully submitted,

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